

502(f) (1)—the labeling of the articles failed to bear adequate directions for use since the labeling failed to state the conditions and purposes for which the articles were intended.

503(b) (1)—the *mephenesin tablets* were dispensed without a prescription.

PLEA: Guilty.

DISPOSITION: 4-21-58. Sentence of 90 days in jail and fine of \$2,250.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5562. Del-Caps. (F.D.C. No. 41316. S. Nos. 70-416/8 M.)

QUANTITY: 1 drum containing 24,850 capsules, 1 drum containing 49,850 capsules, and 1 drum containing 20,300 capsules at Philadelphia, Pa.

SHIPPED: 7-3-57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: (24,850-capsule lot) "Lot No. 2881 * * * Formula Del-Caps 10 Mg."; (49,850-capsule lot) "Del-Caps 15 Timed Disintegration Capsule * * * Each Capsule Contains: Dextro Amphetamine Sulfate 15 mg. * * * provides for the disintegration of the contents throughout a period of 6-10 hours" and "Lot No. 2974 * * * Formula: Del-Caps 15 mg."; (20,300-capsule lot) "Lot No. 2974 * * * Formula: Del-Caps 15 mg.," "Del-Caps Time Disintegration Capsules * * * Dextro amphetamine sulfate 10 mg. * * * provides for the disintegration of the contents throughout a period of 6-10 hours," and "Del-Caps 15 Timed Disintegration Capsule * * * Dextro amphetamine sulfate 15 mg. * * * provides for the disintegration of the contents throughout a period of 6-10 hours."

RESULTS OF INVESTIGATION: Examination showed that the capsules in the 24,850-capsule lot contained 15 mg. per capsule of dextro-amphetamine sulfate, of which 80 percent was released within 1 hour rather than uniformly over a 6- to 10-hour period; that the capsules in the 49,850-capsule lot contained 15 mg. per capsule of dextro-amphetamine sulfate, of which 81 percent was released within 2 hours rather than uniformly over a 6- to 10-hour period; and that the 20,300-capsule lot contained 10 mg. per capsule of dextro-amphetamine sulfate, of which 90 to 99 percent was released within 2 hours rather than uniformly over a 6- to 10-hour period.

LBELED: 1-3-58, E. Dist. Pa.

CHARGE: 501(c)—when shipped, the quality of the article in all lots fell below that which it purported and was represented to possess since the capsules failed to disintegrate as indicated; 502(a)—the statement "Timed Disintegration Capsules * * * provides for the disintegration of the contents throughout a period of 6-10 hours" on the labels of the 49,850- and 20,300-capsule lots was false and misleading; 502(e) (2)—the label of the capsules in the 24,850-lot failed to bear the common or usual name of each active ingredient; and 503(b) (4)—the capsules in the 24,850-capsule lot were a drug subject to 503(b) (1), and the label failed to bear the statement "Caution: Federal law prohibits dispensing without a prescription."

DISPOSITION: 2-26-58. Default—destruction.